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TSO_3 Chemical Indicator
510(k) Summary - K021161

Applicant's Name and Address

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Contact United States Agent

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Submission Date

April 5, 2002

Trade Name

TSO_3 Chemical Indicator

Common Name

Chemical sterilization process indicator

Classification Name

Physical/chemical process indicator is classified as Class II under Sterilization Process Indicator in 21 CFR 880.2800 by the General Hospital and Personal Use Devices Panel.

Legally Marketed Equivalent Device Name(s)

STERRAD® Chemical Indicator

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INDICATIONS-FOR-USE

The TSO_3 Chemical Indicator is a process indicator intended for use by healthcare providers to accompany sterilization packs, containers, or trays intended to be sterilized in the TSO_3, Model *125L* Sterilizer. It is intended to differentiate between unprocessed items and processed items. The color of the TSO_3 Chemical Indicator changes from a red to lighter than the peach reference color when exposed to ozone, a critical component of the TSO_3 Model *125L* Sterilizer sterilization process.

Description of Device

The TSO_3 Chemical Indicator is a process indicator strip intended to be used in the TSO_3-*125L* Ozone Sterilizer. The TSO_3-*125L* Ozone Sterilizer uses Ozone vapor at low temperature and high humidity to destroy both spore-forming and nonspore-forming microorganisms. The routine use of CI's is considered to complement the employment of a biological indicator monitoring program. The TSO_3 Chemical Indicator can be used to identify that an item has been processed through the TSO_3-*125L* Ozone Sterilizer and that the Ozone was present. It does not imply that terminal sterilization occurred or to assure that the sterilization cycle has been completed.

The Indicator Strip

The TSO_3 Chemical Indicator is comprised of a paper strip upon which a reactant chemical indicator ink is printed which is then overcoated with a clear finish to prevent the indicator ink from being damaged by handling or abrasion before, during or after use. The imprint consists of a red indicating ink circle located within a peach colored reference square. When the color of the indicator circle has changed to a color lighter than that of the surrounding peach colored reference square, the appropriate exposure to Ozone has taken place.

Packaging

The TSO_3 Chemical Indicator strips are packaged in rolls of 1000 indicators adhesively affixed to the roll to be peeled off for use. The rolls are packaged 2 per box for distribution.

Performance testing

The TSO_3 Chemical Indicator is intended for one time, single use by health care workers to differentiate processed from unprocessed items.

Performance testing to support a substantial equivalence decision include the following :

Incremental exposures to ozone - For the CI to reach its end point, the ozone dose injected into the sterilization chamber (ozone concentration) must be at least 70 mg/L.

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Effects of other chemicals on the TSO_3 Chemical Indicator color pre and post exposure to ozone :

Tests were conducted to determine the effect of acid and basic vapors and solutions on the color stability of the Chemical Indicators. Generally, with the exception of liquids and very strong alkaline vapors, the color stability was not effected.

The effect of UV exposure on color stability of the TSO_3 Chemical Indicator was evaluated for pre and post exposure to ozone. Unprocessed CIs were exposed to UV for 15, 30, 45 and 60 days. The unprocessed CI's color was not affected by UV exposure. The color of the CI is stable to UV up to 2 months after being processed in a partial sterilization cycle. A slight color difference is observed for CIs processed to a partial sterilization cycle when exposed to UV between 3 to 12 months.

The effects of other sterilization processes on the color stability of the TSO_3 Chemical Indicator were evaluated:

CIs were processed to an EtO sterilization cycle and the CI color is not affected by EtO sterilization process.

CIs were also processed to 2 different (liquid and porous load) Steam sterilization cycles. Results indicate that the CI color is effected by a liquid cycle in an autoclave but not affected by a porous load cycle.

Cytotoxicity tests were conducted to determine if residues could be released by the CI when exposed to the sterilization cycle. CI's were processed in contact with polymer (LDPE), Stainless Steel coupons and medical grade silicone inside a sterilization pouch. Results showed that the CI does not induce cytotoxicity.

Conclusion

The results of the performance studies with the TSO_3 Chemical Indicator demonstrated that the TSO_3 Chemical Indicator is appropriate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

Technologies of Sterilization with Oxone, TSO3 Incorporation
C/O Mr. Charles O. Hancock, RAC
President
Charles O. Hancock Associates, Incorporated
33 Black Watch Trail
Fairport, New York 14450-3701

Re: K021161
Trade/Device Name: TOS_3 Chemical Sterilization Process Indicator
Regulation Number: 880.2800 (b)
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: August 18, 2003
Received: August 20, 2003

Dear Mr. Hancock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use Statement
510(k) Number K021161

Device Name : TSO_3 Chemical Indicator

Indications for Use :

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021161